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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,884	03/21/2001	Russell John Mumper	50229-262	1135
7590		12/29/2005	EXAMINER	
Michael C Barrett		YOUNG, MICAH PAUL		
Fulbright & Jaworski LLP		ART UNIT		
600 Congress Avenue		PAPER NUMBER		
Suite 2400		1618		
Austin, TX 78701		DATE MAILED: 12/29/2005		

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/812,884

Applicant(s)

MUMPER ET AL.

Examiner

Micah-Paul Young

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

**Acknowledgement of Papers Received:** Request for Continued Examination dated 9/30/05.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 21-23,25,27 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by de Vringer (EP 0 506 197 hereafter '197). The claims are drawn to a method of making a solid nanoparticle comprising making an oil-in-water emulsion by heating where the emulsion comprises a nanoparticle matrix material, a surfactant or co-surfactant and a molecule of interest; a cooling the microemulsion.

3. The '197 patent teaches a method for making an aqueous suspension of a solid lipid nanoparticle (abstract). The method includes melting an appropriate quantity of a solid lipid in the presence of an emulsifier; vigorously dispersing the molten lipid and allowing it to cool resulting in solid lipid nanoparticles ranging in size from 50-1000 nm (pg. 2, lin. 45-pg. 3, lin. 5; pg. 4, lin. 29-46). The temperature for heating the solid material is sufficient to melt the lipid and ranges from 30-100 degrees Celsius (pg. 3, lin. 40-44). The cooling, and stirring occurs at room temperature (examples). The solid lipids include waxes, hydrocarbons, synthetic esters, higher fatty acids such as stearic acid, and mono-, di and triglycerides of higher fatty acids (pg. 3, lin. 45-55). The emulsifiers include polyoxyethylene alkyl esters, sorbitan esters, polyoxyethylene fatty acids and the like (pg. 4, lin. 5-23). The mixture comprises a continuous

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phase comprising water (pg. 4, lin. 25-28). Medicament can be used in or with the suspension of solid nanoparticles that range from antibiotics to anti-inflammatory agents (pg. 5, lin. 1-10, example 4). These disclosures render the claims anticipated.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 24,26,28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of de Vringer (EP 0 506 197 hereafter '197).

7. As discussed above the '197 patent discloses a method of making a solid nanoparticle by heating and cooling an oil-in-water emulsion. The reference also teaches the particular ranges of the components, but the ranges are recited in different manners as that of the instant claims. However, the '197 patent discloses the liquid nanoparticle matrix in concentration from 0.01-60% w/w, the emulsifier is present in a concentration from 0.01-20% w/w and a balance of water

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as a buffer and a concentration of an active molecule of interest. The result of this method is a solid lipoid nanoparticle suspension. The general conditions of the claims have been met by the disclosures of the art. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

8. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various cosmetic compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

9. With these things in mind it would have been motivated to follow the teachings of the '197 patent in order to maximize and optimize the method in order to produce a better product. It would have been obvious to follow these teachings and suggestions with an expected result of a solid nanoparticle suspension formulation.

***Response to Amendment***

10. The declaration under 37 CFR 1.132 filed 9/28/05 is insufficient to overcome the rejection of claims 21-30 based upon 35 USC 102(e) as set forth in the last Office action because: New art has been found. Also, the declaration is drawn to specific examples using only emulsifying wax, while the claims are drawn to any and every solid matrix material. The experiments of the declaration are not commensurate with the scope of the broad claim.

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*Response to Arguments*

11. Applicant's arguments with respect to claims 21-30 have been considered but are moot in view of the new ground(s) of rejection.

*Correspondence*


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
MP Young

Micah-Paul Young  
Examiner  
Art Unit 1618

  
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